GP 1655

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G. Gundling, et al.

Application No.: 09/492,213

Filed: January 27, 2000

Title: METHOD OF PROCESSING A SAMPLE CONTAINING AT LEAST ONE BIOLOGICAL ELEMENT

Case No.: 6416.US.P1

Group Art No.: 1655

Examiner: B. Sisson

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents Washington, D.C. 20231, on:

Date of Deposit: February 05, 2001

Julie Freeman 02-05-01
Julie Freeman Date

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

TRANSMITTAL LETTER

Enclosed herewith for the patent application identified above entitled METHOD OF PROCESSING A SAMPLE CONTAINING AT LEAST ONE BIOLOGICAL ELEMENT are the following:

1. Request for Reconsideration
2. Request for Extension of Time, in duplicate
3. Return Receipt Postcard

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 C.F.R. § 1.16, as well as any patent application processing fees under 37 C.F.R. § 1.17 associated with this communication for which full payment had not been tendered, to Deposit Account No. 01-0025.

Dated: February 05, 2001

Respectfully submitted,
G. Gundling, *et al.*

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G. Gundling, *et al.*

Application No.: 09/492,213

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Title: METHOD OF PROCESSING A SAMPLE CONTAINING AT LEAST ONE BIOLOGICAL ELEMENT

Case No.: 6416.US.P1

Group Art No.: 1641

Examiner: B. Sisson

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Julie Freeman 02-05-01
Julie Freeman Date

Assistant Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION

In response to the Office Action dated August 10, 2000, please consider the following remarks.

Six independent claims are pending in this application, all of which stand rejected.

The sole ground of rejection is that the claimed methods allegedly are not supported by an enabling disclosure. Specifically, the Office Action alleges that (i) it "is clear that the claims encompass the manipulation of nucleic acids and that these nucleic acids can be brought together for hybridization or be separated from each other so as to retard any amplification reaction," (ii) as set forth in the Carrico '313 patent various conditions, such as, purity of the preparation, G-C base content, ionic strength of the buffer, and others, affect the extent and specificity of hybridization, and (iii) the applicants' specification does not disclose these conditions. Applicants respectfully traverse.

The enablement rejection is tailored to the Patent Office's definition of the pending claims, which is quoted above. The pending claims, however, are more precisely drafted. Consideration of the differences between the pending claims and

the Patent Office's definition of the pending claims reveals why the enablement rejection should be withdrawn.

Claims 1 and 4 are directed to a method that reduces the ability of a biological element in the sample to be amplified or detected in a PCR reaction. Importantly, the claimed method does not require bringing nucleic acids together for hybridization. Indeed, the claimed method may *reduce the ability* of a nucleic acid in the sample to hybridize such that it is more difficult to amplify or detect in a PCR reaction.

While the *minimum* electrical requirements to achieve this result may vary depending on such things as the purity of the preparation, G-C base content, ionic strength of the buffer, and other variables that the Office Action identifies, there is no evidence of record (including in Carrico '313 patent) that the skilled artisan having benefit of applicants' disclosure would have any difficulty in identifying parameters suitable to achieve the claimed result.

Moreover, the specification provides the ordinarily skilled artisan with ample guidance in the practice of the full scope of the claimed method. For example, a circuit suitable for practicing the claimed method is disclosed in the specification at, e.g., page 53, line 23, to page 56, line 2. Exemplary parameters for operating this circuit sufficient to achieve the claimed result are also given in the specification at page 56, lines 19-26. If so desired, the skilled artisan can modify these parameters in order to make the claimed invention work better. However, there is no reason of record to suspect that the claimed method does not work.

Similarly, claims 2 and 5 are directed to a method that results in the disruption of binding between a biological element and a binding member, and claims 3 and 6 are directed to a method that results in the unzipping of a biological element (e.g., a DNA) in the sample. Again, the claimed method does not recite that any nucleic acids are brought together for hybridization, and to the extent that nucleic acids are involved, the claimed method can only be read to reduce the ability of these nucleic acids to hybridize.

Likewise, the *minimum* electrical requirements to achieve these results *may* vary depending on variables identified in the

Office Action, but there is no evidence of record that the skilled artisan would have any difficulty identifying a *suitable* set of parameters that would result in a *decrease* in the ability of a biological element in the sample to be amplified or detected in a PCR reaction process.

For the foregoing reasons, applicants respectfully request that the enablement rejection be withdrawn and this application be passed to issue.

Applicants also traverse the enablement rejection on the basis that the Office Action does not establish prima facie support for the rejection. The Office Action merely notes (as is known in the art and reflected by the Carrico '313 patent) that various parameters of a composition affect the ability of nucleic acids to hybridize and/or participate in PCR. This might conceivably support an enablement rejection if the claimed method comported with the Office Action's summary of the claimed invention. However, The Office Action does not show why or how these parameters cast a reasonable doubt on the ability of the skilled artisan to: (i) "reduce the ability of a biological element to be amplified or detected in a PCR reaction process" (claims 1 and 4) (ii) remove a biological element from a binding member (claims 2 and 5), and/or (iii) unzip a biological element in a sample (claims 3 and 6). Accordingly, the present enablement rejection should be withdrawn for the additional reason that prima facie support for the rejection has not been established.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution, the Examiner is invited to call applicants' undersigned representative.

Dated: February 5, 2001

Respectfully submitted,
G. Gundling, *et al.*

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